

*Only for the use of medical professionals*

## SOLONE®

Prednisolone

### Description

SOLONE® is a preparation of Prednisolone is a synthetic glucocorticoid (corticosteroid). Prednisolone is more biologically active form of prednisone metabolized in liver, useful for the treatment of a wide range of inflammatory and auto-immune conditions. Prednisolone crosses cell membranes and binds with high affinity to specific cytoplasmic receptors. The result includes inhibition of leukocyte infiltration at the site of inflammation, interference in the function of mediators of inflammatory response, suppression of humoral immune responses, and reduction in edema or scar tissue.

### Indications and usage

SOLONE® is indicated in the treatment of -

- **Allergy & anaphylaxis:** Bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema, anaphylaxis.
- **Arteritis/collagenosis:** Giant cell arteritis/polymyalgia rheumatica, mixed connective tissue disease, polyarteritis nodosa, polymyositis.
- **Blood disorders:** Haemolytic anaemia (autoimmune), leukaemia (acute & lymphocytic), lymphoma, multiple myeloma, idiopathic thrombocytopenic purpura.
- **Cardiovascular disorders:** Post myocardial infarction syndrome, rheumatic fever with severe carditis.
- **Endocrine disorders:** Primary & secondary adrenal insufficiency, congenital adrenal hyperplasia.
- **Gastro-intestinal disorders:** Crohn's disease, ulcerative colitis, persistent celiac syndrome, autoimmune chronic active hepatitis, multisystem disease affecting liver, biliary peritonitis.
- **Infections:** Miliary tuberculosis, mumps orchitis (adult), tuberculous meningitis, rickettsial disease.
- **Muscular disorders:** Polymyositis, dermatomyositis.
- **Neurological disorders:** Infantile spasms, Shy-Drager syndrome, sub-acute demyelinating polyneuropathy.
- **Renal disorders:** Lupus nephritis, acute interstitial nephritis, minimal change glomerulonephritis.
- **Respiratory diseases:** Allergic pneumonitis, asthma, occupational asthma, pulmonary aspergillosis, pulmonary fibrosis, pulmonary alveolitis, aspiration of stomach contents, aspiration of foreign body, pulmonary sarcoidosis, drug induced lung disease, adult respiratory distress syndrome, spasmodic croup.
- **Rheumatic disorders:** Rheumatoid arthritis, polymyalgia rheumatica, juvenile chronic arthritis, systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease.
- **Skin disorders:** Pemphigus vulgaris, bullous pemphigoid, systemic lupus erythematosus, pyoderma gangrenosum.
- **Miscellaneous:** Sarcoidosis, hyperpyrexia, Behcet's disease, immunosuppression in organ transplantation.

## Dosage and administration

The initial dose of SOLONE® may vary from 5 mg to 60 mg daily depending on the disorder being treated. Divided daily dosage is usually used.

Children:

Disease	Dose
Acute asthma	1-2 mg/kg/day in single or divided doses for 3-10 days
Anti-inflammatory condition	0.1-2 mg/kg/day in three or four divided doses
Nephritic syndrome	2 mg/kg/day in three divided doses for 4 weeks, followed by 4 weeks of single dose alternate day therapy at 1 mg/kg/day

The appropriate individual dose must be determined by trial and error and must be re-evaluated regularly according to activity of disease.

In general, initial dose shall be maintained or adjusted until the anticipated response is observed. The dose should be gradually reduced until the lowest dose which will maintain an adequate clinical response is reached.

During prolonged therapy, dosage may need to be temporarily increased during periods of stress or during exacerbations of disease. When the drug is to be stopped, it must be withdrawn gradually and not abruptly.

*Intermittent dosage regimen:* A single dose of SOLONE® tablet in the morning on alternate days or at longer intervals is acceptable therapy for some patients.

*Specific dosage guidelines:*

Disease	Initial dose
Allergic and skin disorders	5-15 mg daily
Collagenosis	20-30 mg daily (May require higher doses in case of more severe symptoms)
Rheumatoid arthritis	10-15 mg daily
Blood disorders & lymphoma	15-60 mg daily is often necessary with reduction after an adequate clinical or haematological response. Higher doses may be necessary to induce remission in acute leukaemia.

## Use in pregnancy and lactation

*Use in pregnancy:* There is evidence of harmful effects of corticosteroids on pregnancy in animals.

*Use in lactation:* Corticosteroids are excreted in small amounts in breast milk. If maternal doses > 40 mg/day of prednisolone, the infant should be monitored for adrenal suppression.

## Use in children

Corticosteroids cause growth retardation in infancy, childhood & adolescence, therefore long-term administration of pharmacological doses should be avoided.

## Side effects

Fluid and Electrolyte Disturbances: Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, hypertension. Musculoskeletal: Muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones. Gastrointestinal: Peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis. Dermatologic: Impaired wound healing, thin fragile skin, petechiae and ecchymoses,

facial erythema, increased sweating, and may suppress reactions to skin tests. Neurological: Convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, vertigo, headache. Endocrine: Menstrual irregularities, development of Cushingoid state. Suppression of growth in children. Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery, or illness. Decreased carbohydrate tolerance. Manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics. Ophthalmic: Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos. Metabolic: Negative nitrogen balance due to protein catabolism.

## Precautions

Drug-induced secondary adrenocortical insufficiency, hypothyroidism, cirrhosis, ocular herpes simplex, ulcerative colitis may be minimized by gradual reduction of dosage.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

Caution should be taken when oral corticosteroids, including Prednisolone, are prescribed in patients with following conditions like-tuberculosis, hypertension, congestive heart failure, liver failure, renal insufficiency, and diabetes mellitus or in those with a family history of diabetes, osteoporosis, patients with a history of severe affective disorders & particularly those with a previous history of steroid-induced psychoses, epilepsy, peptic ulceration, and previous steroid myopathy.

## Contraindications

Prednisolone is contraindicated in patients with hypersensitivity to prednisolone, systemic infections unless specific anti-infective therapy is employed and ocular herpes simplex because of possible perforation.

## Drug interactions

**Hepatic microsomal enzyme inducers:** Drugs that induce hepatic enzyme (e.g., phenobarbital, phenytoin, rifampicin, carbamazepine) may reduce the therapeutic efficacy of by increasing rate of metabolism, thus may require increased glucocorticoid dose to achieve the desired response. **Hepatic**

**microsomal enzyme inhibitors:** Drugs that inhibit hepatic enzyme (e.g., ketoconazole, troleandomycin) may inhibit the metabolism of glucocorticoid thus decrease their clearance. Therefore, the dose of glucocorticoid should be titrated with to avoid steroid toxicity. **Non-steroidal anti-**

**inflammatory drugs:** Concomitant administration of ulcerogenic drugs such as indomethacin during corticosteroid therapy may increase the risk of GI ulceration. Aspirin should be used cautiously in conjunction with glucocorticoids in patients with hypoprothrombinaemia. Although concomitant therapy with salicylate and corticosteroids does not appear to increase the incidence or severity of GI ulceration, the possibility of this effect should be considered. Serum salicylate concentrations may decrease when corticosteroids are administered concomitantly. The renal clearance of salicylates is increased by corticosteroids and steroid withdrawal may result in salicylate intoxication. Salicylates and corticosteroids should be used concurrently with caution. **Anti-diabetic drugs:** Glucocorticoids may increase the blood glucose levels. Patients with diabetes mellitus receiving concurrent insulin and/or oral hypoglycemic agents may require dosage adjustments of such therapy. **Anti-coagulants:** Response to anti-coagulants may be reduced or, less often, enhanced by corticosteroids. Close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding.

## **Overdose**

Reports of acute toxicity and/or death following overdose of glucocorticoids are rare. No specific antidote is available; treatment is supportive and symptomatic. Serum electrolytes should be monitored.

## **Pharmaceutical precautions**

Keep away from the reach of children. Store in a cool and dry place protected from light. To be taken and sold only on the prescription of a registered physician.

## **Presentation**

SOLONE<sup>®</sup> 5 tablet : Each enteric coated tablet contains Prednisolone BP 5 mg.  
SOLONE<sup>®</sup> 10 tablet : Each enteric coated tablet contains Prednisolone BP 10 mg.  
SOLONE<sup>®</sup> 20 tablet : Each enteric coated tablet contains Prednisolone BP 20 mg.  
SOLONE<sup>®</sup> Oral Solution : Each 5 ml solution contains Prednisolone Sodium Phosphate USP equivalent to Prednisolone 5 mg.

## **Package quantities**

SOLONE<sup>®</sup> 5 tablet : Carton of 100 tablets in blister pack.  
SOLONE<sup>®</sup> 10 tablet : Carton of 100 tablets in blister pack.  
SOLONE<sup>®</sup> 20 tablet : Carton of 50 tablets in blister pack.  
SOLONE<sup>®</sup> oral solution : Bottle of 50 ml & 100 ml with measuring cup.

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